

DETAILED ACTION

The amendment filed 16 February 2010 is acknowledged and has been entered. Claims 11, 13-22, and 25-29 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 11, 13, 14, 20, 21, and 27-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Withcl (1994 - reference cited by Applicants in the IDS submitted 2/20/2007).

Withcl beneficially teaches preparing an aqueous extract composition from the leaves of *Castanea sativa*. In addition, this reference teaches that such *Castanea sativa* leaf extract preparations have been incorporated into various prior art pharmaceutical compositions which would intrinsically comprise one or more of the cosmetic and/or dermatopharmaceutical auxiliaries and/or additives therein - such as a stabilizer, hydrotrope, solubilizer, preservative, and/or dye (see page 133, third column under the headings ***Making the tea*** and ***Phytomedicines***), or it would have at least been obvious for one of ordinary skill in the pharmaceutical art to do so to (especially given the numerous broad auxiliaries/additives which can be added thereto - as instantly claimed).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic composition comprising an aqueous extract of *Castanea sativa* leaves as the active ingredient therein, based upon the beneficial teachings provided by the cited reference. The adjustment of particular conventional working conditions (e.g., determining an appropriate concentration of such a leaf extract and/or adding commonly

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employed auxiliaries/additives - many of which would also read upon cosmetic auxiliaries/additives - thereto) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

Applicants' arguments as they pertain to the art rejection above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that it is clear that the auxiliaries/additives added to a phytomedicine (specifically as disclosed by Withcl to be antitussives and expectorants) are designed to be taken internally to the human body, would not be the same auxiliaries/additives added to a cosmetic or dermatopharmaceutical designed to be administered topically to the body surface such as the skin, hair, or nails. However, please note that nothing would preclude topical administration of the various pharmaceutical forms disclosed by Withcl - i.e., nothing would preclude these various internal prior art *Castanea sativa* leaf extract-containing phytomedicines from being topically applied to the skin (including the drops and juice forms taught therein) and that such pharmaceutical forms would intrinsically or at least typically comprise one or more of the auxiliaries/additives instantly claimed - including conventional auxiliaries/additives incorporated within antitussives, expectorants, and/or oral drops/juices thereof) such as stabilizers, hydrotropes, solubilizers, preservatives, and/or dyes. In the alternative (i.e., if not intrinsic) - as stated above, it would have at least been obvious for one of ordinary skill in the pharmaceutical art to do so to especially given the numerous broad auxiliaries/additives which can be added thereto (as instantly claimed).

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Claims 11, 13-22, and 25-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chiej (MacDonald Encyclopedia of Medicinal Plants, 1984) in view of Grand (US 3,849,548) and the admitted state of the art, with evidence provided by Chevallier (Encyclopedia of Herbal Medicine, 2000)*.

Chiej teaches that a hair shampoo comprising an extract (e.g., in the form of an infusion or other fluid extract) of *Castanea sativa* leaves is well known in the art to impart a golden gleam to the hair, and that *Castanea sativa* leaves have been used in the prior art as a substitute for witch hazel (see # 72 - herbal description of *Castanea sativa*). As evidenced by Chevallier, infusions are prepared via placing the plant/herbal material in a strainer, then placing the strainer in hot/boiling water for 5-10 minutes, removing the strainer (with the plant/herbal material inside) to produce the extract infusion (see page 291 of Chevallier). Further, as evidenced by Chevallier, witch hazel is notoriously well known in the prior art to be used cosmetically to topically treat such ailments as skin abrasions, facial veins, varicose veins, and hemorrhoids, including in the form of a lotion or ointment (see page 104 of Chevallier).. Thus, the infusion of *Castanea sativa* leaves (within such a hair shampoo and/or cosmetic) as reasonably taught/suggested by Chiej reads upon the instantly claimed *Castanea sativa* leaf extract and preparatory method thereof. Chiej does not appear to expressly teach the inclusion of one or more of the auxiliaries/additives instantly claimed within such a hair shampoo or cosmetic product comprising *Castanea sativa* leaf extract therein.

Grand teaches cosmetic hair/skin care products including in the form of a cleansing hair (shampoo) and/or skin composition (containing surfactants therein) which may further comprise

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other adjuvants/substances therein such as plant extracts including so to enhance the cosmetic properties thereof (see entire document including col 4, lines 56-61 and col 9, lines 34-41).

Further, as readily admitted by Applicants, the instantly claimed auxiliaries/additives are well known in the art to be common for cosmetic purposes.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a hair shampoo comprising an effective amount of a *Castanea sativa* leaf extract (such as in the form of an infusion) as an active cosmetic ingredient therein with respect to functioning to impart a golden gleam to the hair (as beneficially taught by Chief) and/or to provide a cosmetic skin care composition comprising an effective amount of a *Castanea sativa* leaf extract so as to function effectively as a substitute for witch hazel when topically applied to an area of skin in need thereof - including within a conventional hair (shampoo) and/or skin care product such as one comprising one or more surfactants therein and/or other admittedly well known conventional cosmetic auxiliaries/additives therein, including a hair (shampoo) and/or skin care product in which plant extracts can be incorporated therein (for their known cosmetic purpose), such as beneficially taught by Grand. The adjustment of particular conventional working conditions (e.g., determining an appropriate amount of an infused *Castanea sativa* leaf extract to incorporate therein and/or using a conventional extraction solvent to prepare such a *Castanea sativa* leaf extract as well as removing the solvent therefrom following extraction so as to form a concentrated extract) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

* Please note that the Chevallier reference is not being cited as art within the USC 103 rejection immediately above, but instead is being cited to show an inherent feature with respect to preparing a plant infusion (e.g., from *Castanea sativa* leaves) such as reasonably taught/suggested by the Chiej reference, as well as to show the well known prior art cosmetic uses of witch hazel (as discussed within the USC 103 rejection above).

Applicants' arguments concerning the USC 103 rejection above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that a full and true reading of Chiej discloses that an infusion or fluid extract of *Castanea sativa* leaves serves as a natural shampoo but that the references does not state that the shampoo comprises an extract of *Castanea sativa*, and that infusions do not include the step of removing the solvent as required by some of the instant claims. However, it would be clear to one of ordinary skill in the art that such an infusion or extract of *Castanea sativa* leaves would be appropriate as an active ingredient (for imparting a golden gleam to the hair) for incorporation into a shampoo formulation (such as a shampoo formulation disclosed by Grand). Further, the removal of solvent from a plant extract (such as an extract of *Castanea sativa* leaves) is a commonly-employed step used within the herbal art in preparing concentrated plant extracts having enhanced and/or more stabilized activity. This type of adjustment is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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Applicant further argues that Grand does not teach a particular plant extract for incorporation within the shampoo taught therein. However, this secondary reference was cited for the teachings discussed above - i.e., Grand teaches cosmetic hair/skin care products including in the form of a cleansing hair (shampoo) and/or skin composition (containing surfactants therein) which may further comprise other adjuvants/substances therein such as plant extracts including so to enhance the cosmetic properties thereof (see entire document including col 4, lines 56-61 and col 9, lines 34-41). [It is noted that Applicants did not argue the admitted state of the art, as discussed within the art rejection above (i.e., as readily admitted by Applicants, the instantly claimed auxiliaries/additives are well known in the art to be common for cosmetic purposes).]

Applicant has argued and discussed references individually without clearly addressing the combined teachings (including the admitted state of the art). It must be remembered that the references (and admitted state of the art) are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon art which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references (and admitted state of the art).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970.

The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655